

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Final Office Action are respectfully requested in view of this amendment. By this amendment, claims 1 and 7 have been amended. Claims 1-18 are pending in this application.

Claims 1 and 7 have been amended in order to describe the administration of the Botulinum toxin such that the Botulinum toxin synergistically interacts with the electromagnetic signals. Support is found, *inter alia*, page 9, line 29 to page 10, line 3 of the present application. It is respectfully submitted that the above amendments introduce no new matter within the meaning of 35 U.S.C. §132.

Rejections Under 35 U.S.C. §103

In the Final Office Action, Claims 1, 2, 6-8, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,443,883 issued to Ostrow et al. ("*Ostrow*") in view of U.S. Patent No. 6,464,986 issued to Aoki et al. ("*Aoki*"). Claims 1, 3, 6, 7, 9, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent Application Publication No. 2004/0077921 applied for by *Becker* et al. ("*Becker*") in view of *Aoki*. Claims 1-5, 7-11, and 13-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 4,674,482 issued to Waltonen et al. ("*Waltonen*") in view of *Aoki*.

Response

This rejection is traversed as follows. As set forth in Applicant's response of June 17, 2008, to establish a *prima facie* case of obviousness, the Examiner must establish: (1) some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) the prior art references teach or suggest all of the claim limitations.

Aoki provides a method for treating pain with Botulinum toxin, whereas *Ostrow* provides a pulsed electro-magnetic field (PEMF) biophysical stimulation field generator device for

accelerating the healing of fractured bones and soft tissues. According to the Final Office Action, a combination of these two would lead to the present application. It is respectfully submitted that the combination fails to show or suggest combining the pain-treatment of *Aoki* with the bone-fracture-treatment of *Ostrow*. Furthermore, the combination fails to show a need for such a combination. As the present application uses a hitherto unknown synergetic effect of the pulsating, magnetic field and the administration of Botulinum toxin, this synergetic effect is now incorporated into independent claims 1 and 7.

This use of the pulsating electromagnetic signals is described, for instance, on page 9, line 29 to page 10, line 3 of the present application:

"In particular, the pulsed signal therapy (PST(R)) is used together with Botulinum toxin... This led to an increase in bone density. It was found that Botulinum toxin, employed as an adjuvant, synergistically interacted with PST(R) specific, pulsating electromagnetic signals, to further enhance its bone density, stimulating potential."

Claims 1 and 7, as presently amended, now set forth the feature of the synergetic interaction to the independent claims. The last part of claim 1 then reads:

"...administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals, such that the Botulinum toxin synergistically interacts with the electromagnetic signals."

Thereby, the claimed subject matter is clearly distinguished from the combination of *Ostrow* and *Aoki*. In particular, the present subject matter more than a mere combination of a pain treatment and a pulsating magnetic field therapy.

With reference to the cited references, it is pointed out that *Ostrow* fails teach the use of electromagnetic signals for enhancing bone density. Therefore *Ostrow* does not teach the treatment of osteoporosis. Instead, *Ostrow* refers only to bone fractures, which may be an effect of osteoporosis; however this approach does not help to treat the causes of osteoporosis, i.e., the decreased bone density.

The same applies to the teaching of *Aoki*. Using Botulinum toxin as pain treatment does not help to cure the causes of the pain.

Therefore, Applicant submits that the combination of *Ostrow* and *Aoki* discloses only a treatment of the symptoms of osteoporosis, but not the causes of osteoporosis. It is known to people skilled in the art knows that curing a disease and curing the symptoms of a disease are two different practices and that, in almost all the cases, a treatment method for the symptoms is not a cure for the disease itself. Thus, a person skilled in the art, looking for a way to treat the causes of osteoporosis (i.e., the low bone density) would not look to the treatment of the symptoms of osteoporosis.

In this particular case, the treatment of the symptoms is generally directed to pain and bone failure. The causes of the disease are not the pain and bone failure.

Applicant submits, as Attachment A, a poster from an osteoporosis congress. This Attachment A is also separately submitted in electronic form under the EFS filing system as EFS Document, ID 3796690. The EFS copy is intended to provide a clearer copy, should the scanning of this Response make Attachment A illegible.

The poster submitted as Attachment A shows further differences between the electromagnetic signals generated by pulsating, impulse-modulated direct current, also known as pulsed signal therapy (PST) used in the present application and the PEMF used by *Ostrow*. This poster is submitted by way of explanation only and not as disclosure material.

The effect of the electromagnetic signals of *Ostrow* and PST are not only different in view of the result. While *Ostrow* ameliorates the bone growth between two fracture sides, thus providing help for building new bone material, the present application increases the bone density, i.e., increasing the transport of minerals etc. to present bones with low density. The bone density stimulating potential is proved in several clinical studies, comprising inter alia a comparison between an untreated part of the body (for instance, a wrist) and a treated one. Referring to the poster (Attachment A), the poster reads in the introduction:

"Biophysically, it has been established that PST emulates the innate physiological and mechanical stresses evoked, and required, in bone formation. It passively induces fluid flow and ionic displacement, thereby generating a piezoelectric ("streaming potential") and eventually activating various signaling network paths – as occurs in mechanotransduction. Increased proteoglycan levels, and collagen synthesis, have been observed in vitro, following stimulation with PST."

Particularly, the bone density stimulating effect of PST as described is enhanced in the present application by using the synergetic effect of a neurotoxin and a PST treatment. Thus, even if a person skilled in the art would combine the teaching of *Ostrow* and *Aoki*, this would not lead to the present subject matter.

Further, regarding the synergetic interaction of Botulinum toxin and the pulsed magnetic field therapy (claims 1 and 7), it is submitted that it is evident that a combination of the cited documents would not lead to the effects of the present application, because this effect was not expectable when reading the cited documents. Therefore, and in light of the arguments provided above, it is submitted that a person skilled in the art would not combine two of these documents.

Applicants therefore respectfully submit that the *Ostrow* and *Aoki* references do not teach or suggest all the features as recited in claims 1, 2, 6-8 and 12-18 of the present invention. It is therefore respectfully submitted that the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claims 1, 3, 6, 7, 9, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over *Becker* in view of *Aoki*. Applicant respectfully traverses this rejection, in view of the amended claims, for the reasons set forth in Applicant's amendment of June 17, 2008. In particular, there is no showing or suggestion in the cited combination of the synergetic effect of the pulsating, magnetic field and the administration of Botulinum toxin.

Claims 1-5, 7-11, and 13-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over *Waltonen* in view of *Aoki*. Applicant respectfully traverses this rejection, in view of the amended claims, for the reasons set forth in Applicant's amendment of June 17, 2008. In particular, there is no showing or suggestion in the cited combination of the synergetic effect of the pulsating, magnetic field and the administration of Botulinum toxin.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-18. Since none of the other prior art of record, whether taken alone or in any combination, discloses or suggests all the features of the claimed subject matter, Applicant respectfully submits that independent claims 1 and 7, and all the claims that depend therefrom, are allowable.

CONCLUSION

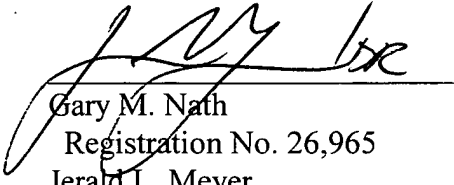
Applicant respectfully submits that all of the stated grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to call the Applicant's undersigned representative at the number below to expedite prosecution.

Respectfully submitted,
THE NATH LAW GROUP

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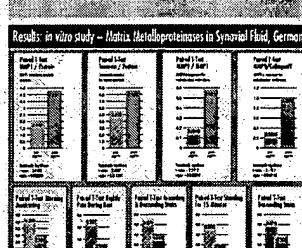
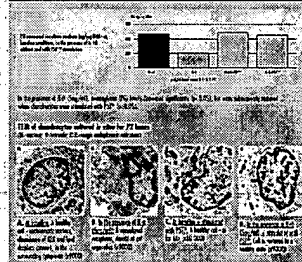


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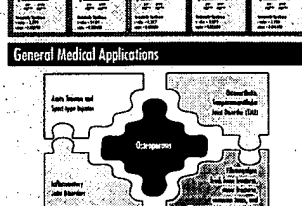
Results: Prospective Multicenter Study (pooled data)

[illegible]

Results: *in vitro* study – Proteoglycan Synthesis: Itol



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11. Emswiler, J.H. Developmental Regulation of the Growth Plate. *J. Cell. Physiol.* 134:393-407, 1978.

[illegible]